

**UNITED STATES DISTRICT COURT  
DISTRICT OF MINNESOTA**

CARPENTERS AND JOINERS  
WELFARE FUND, UNIVERSAL CARE  
INC., NANCY GERDTS individually and  
for minor A.G., CINDY SLAVENS  
individually and for minor J.S., ALAN and  
LAURISSA CHILSON, LEIGH ANN  
ENGH, DARCENE and GREG LENSING,  
on behalf of themselves and all others  
similarly situated,

Plaintiffs

v.

SMITHKLINE BEECHAM  
CORPORATION d.b.a.  
GLAXOSMITHKLINE and  
GLAXOSMITHKLINE plc,  
Defendants

CIVIL ACTION

No. CV 04-3500 MJD/SRN

**MEMORANDUM IN SUPPORT OF JOINT MOTION FOR  
FINAL APPROVAL OF CLASS ACTION SETTLEMENT**

**INTRODUCTION**

Following months of negotiation and years of litigation, counsel for Carpenters and Joiners Welfare Fund and Universal Care, Inc., individually and in their capacities as class representatives (“Plaintiffs”) and counsel for SmithKline Beecham Corporation d/b/a GlaxoSmithKline (“GSK”) reached a settlement (“Settlement”) to conclude this litigation, subject to the Court’s approval. As discussed in greater detail below, the Settlement provides substantial benefit to the members of the putative settlement class (“Settlement Class Members”).

The Settlement is a fair resolution of four, separate, purported class action cases, filed in different jurisdictions, that sought a refund of monies paid by Third-Party Payors who purchased, paid, or reimbursed for Paxil® (in tablet and suspended form) or Paxil CR® (as used herein, “Paxil®” includes all forms) prescriptions to persons under the age of 18 years between January 1, 1998 and December 31, 2004. Each case was substantively and procedurally complex. The Settlement was reached only after substantial discovery and litigation had taken place over the course of nearly four years. The Settlement was crafted by very experienced counsel on both sides. Counsel for the plaintiffs in those four cases were all involved in negotiating the Settlement and all support this Motion for Approval. The Settlement involves a payment by GSK of \$40 million to resolve the claims.

Now, plaintiffs and defendant jointly move for the Court’s final approval. The reaction of the class, summarized below, reinforces the Court’s previous finding when entering preliminary approval, that the settlement is fair, reasonable and in the best interests of the class.

## **I. PROCEDURAL HISTORY**

Each of the four cases leading to this Settlement was complex and hotly contested by GSK from the outset. The procedural history of each case will be summarized in separate sections below. Docket sheets for each action were filed with the Preliminary Approval motion, and the efforts of counsel will be described in more detail in the separate Motion for counsel fees.

**A. Carpenters & Joiners Health & Welfare Fund (formerly Gerdt's)**

The case at bar was filed in August 2004, by Nancy Gerdt's as the class representative plaintiff. GSK filed a motion to dismiss in 2004, sought interlocutory appeal after that motion was denied in 2005, and brought a motion for summary judgment in 2007. Discovery was bifurcated, allowing only limited discovery relating to class certification issues. Nonetheless, Plaintiffs' counsel sought and obtained significant discovery. Through a Freedom of Information Act request, Plaintiffs' counsel obtained thousands of pages of documents from the NY Attorney General litigation against GSK relating to pediatric prescriptions of Paxil®. Additionally, two lawyers and a consulting expert in clinical trial management spent several days on site at the GSK facility in Philadelphia, reviewing documents relating to the marketing and clinical testing of Paxil®. This review covered literally tens of thousands of documents and resulted in thousands of pages of documents being produced. GSK also produced several banker's boxes of documents in addition to the documents reviewed at GSK.

Plaintiffs' counsel hired an expert clinical psychiatrist to render opinions relating to GSK's conduct in promoting Paxil® for pediatric use. This consultation, with Dr. Harold Bursztajn, Clinical Professor of Psychiatry at Harvard Medical School, proceeded to the point that he had completed, but not yet filed, an expert affidavit. The day before expert disclosures were due, the matter was stayed pending settlement discussions.

In 2007, GSK settled the individual consumer claims. In 2008, the Gerdt's complaint was amended to include the Carpenters & Joiners Welfare Fund and Universal Care, Inc. as additional class representatives and named plaintiffs.

**B. Carpenters & Joiners Health & Welfare Fund (formerly Engh)**

The *Engh* case was filed in the District Court of Hennepin County, Minnesota, on August 30, 2004. GSK made a Rule 12 motion to dismiss and the court denied that motion. Discovery in *Engh* was coordinated with the *Smith* case in California state court, thereby providing counsel access to the documents and depositions gathered there. GSK has produced hundreds of thousands of documents and the parties have had several discovery disputes, including discovery motions. The plaintiffs in *Engh* filed their motion for class certification in the fall of 2006 but the case was stayed shortly thereafter when GSK settled the individual consumer claims.

In early 2007, the Carpenters & Joiners Health & Welfare Fund was added as a class representative. On July 23, 2007, GSK removed the case to this Court, where it was assigned to Hon. Michael J. Davis as a related case to the pending Gerdt's litigation. After removal, GSK filed a motion to dismiss, and the plaintiffs filed a timely motion to remand.

This Court granted the motion to remand the case to state court. GSK then sought permission to file an interlocutory appeal with the Eighth Circuit Court of Appeals, which was denied for lack of jurisdiction. Discovery then continued in state court and the plaintiffs' motion for class certification was due to be filed. Further proceedings in state court have been held in abeyance pending the settlement negotiations that led to the present motion.

To facilitate settlement, the named plaintiffs from this state court case were joined in the present lawsuit so that this Court may provide a complete disposition of all disputes among the parties involved.

**C. Universal Care (formerly Smith)**

The *Smith* case, as originally known, was filed on June 21, 2004 in the Superior Court of Orange County, California. This case was extensively litigated for almost four years and involved over 24 motions, including a motion for remand, three separate motions to dismiss (demurrers), one motion for judgment on the pleadings and a motion for class certification, the timing of which was negotiated for over 12 months.

The plaintiffs' counsel in Smith took 15 depositions of defense employees or witnesses. Following the settlement of the individual consumer claims in 2007, the plaintiff amended her complaint to add Universal Care, Inc. as a named plaintiff and putative class representative. Discovery continued. GSK's counsel took 3 person-most-knowledgeable depositions of entity plaintiff UCI. The plaintiffs' counsel issued 9 sets of document requests and UCI responded to multiple interrogatories and requests for production. The plaintiffs' counsel issued 35 deposition subpoenas and reviewed, analyzed and categorized hundreds of thousands of pages of documents. The plaintiffs' counsel retained and prepared 11 experts, including obtaining detailed written reports for the class certification motion. Additional details of the efforts made in this case are contained in the declaration filed by attorney Michael Baum, which is attached to the separate Motion for approval of plaintiff's counsel fees.

**D. Philadelphia Firefighters Local 22 Health and Welfare Fund**

Initially filed in the Court of Common Pleas of Philadelphia on May 16, 2007, this action was removed to the United States District Court, where it was assigned to Hon. James T. Giles. GSK filed a Motion to Dismiss the Complaint, raising numerous defenses which, it contended, showed as a matter of law that the plaintiffs had not stated a claim. GSK attacked the plaintiff's standing, on grounds that the complaint did not show "injury in fact" or a causal connection between GSK's alleged misconduct and the alleged damages. In this connection, GSK vigorously argued that prescriptions of Paxil® resulted from the independent prescribing decisions of physicians, and that GSK had not made any representations to the plaintiffs themselves.

GSK also argued that the plaintiffs did not have a private cause of action under Pennsylvania's consumer protection statute. Their arguments included contentions that the Fund did not purchase medication for "personal or family purposes," as required by the statute's terms, and because the statute did not apply to representations made to physicians, who were learned intermediaries. GSK contended that the Complaint's theories of implied warranty and unjust enrichment were invalid in the prescription drug context, where the Fund did not receive the alleged misrepresentations, and hence could not rely on them.

Several rounds of briefing followed, with the plaintiffs' Answer, Defendant's Reply, a Surreply from the plaintiffs. GSK filed a Supplemental Memorandum, adding a defense of implied conflict pre-emption, based on a newly issued opinion from the Court of Appeals for the Third Circuit. The plaintiff responded to that brief as well. The

Motion to Dismiss remains fully briefed and pending. Judge Giles had scheduled oral argument on the Motion. That hearing was continued at the parties' request, when the settlement negotiations began to become productive.

## **II. SETTLEMENT NEGOTIATIONS**

The Settlement before the Court was reached following extensive arms' length negotiations involving seven different law firms on Plaintiffs' side and national counsel for GSK on the other. Those negotiations took place following and during the vigorous litigation described above. The settlement negotiations took place over the better part of the year with in-person meetings in Atlanta, Philadelphia, New York and Minneapolis. In between these in-person negotiations, countless proposals and counterproposals were dispatched between Plaintiffs and GSK's counsel, by telephone and email.

Literally hundreds of thousands of documents, numerous depositions, and multiple hearings in the different cases gave all counsel full knowledge of the strengths and weaknesses of these claims and have resulted in this Settlement, which all Plaintiffs' counsel believe is an excellent result for the class. The Settlement was reached as the parties prepared for imminent class certification hearings in the Smith and Engh cases, as well as oral argument in the Firefighters case on GSK's Motion to Dismiss.

After preliminary approval and class notice was given, further discussions among the parties were triggered by the receipt of exclusions and one set of objections. The nature of these exclusions and objections will be discussed below. Through multi-party negotiations, two modifications were made to the settlement as initially proposed, which will benefit class members. As a result of these modifications, most of the exclusions

will be withdrawn, and the objections satisfied. These modifications have been submitted for preliminary review and approval by a separate motion.

### **III. THE PROPOSED SETTLEMENT**

The following summarizes the principal terms of the Settlement:

- GSK will pay a settlement amount of Forty Million Dollars (\$40,000,000) (“Settlement Amount”);
- Settlement Class Members will be able to claim a refund calculated as 40% of their actual cost for Paxil® prescribed to minors with a diagnosis of Major Depressive Disorder, or 15% if that diagnosis is not shown;
- Attorneys’ fees and costs, and incentive payments to named plaintiff, subject to Court approval as sought in a separate Motion, will be paid from the Settlement Amount. Costs of class notice and administration will also be paid from the Settlement Amount;
- If, after all claims, costs, and fees are paid, the Settlement Amount has not been exhausted, the balance will *not* revert to GSK. The first \$1,000,000 of any unclaimed balance will be donated to a suitable charitable organization involved with children’s mental health ( to be proposed by GSK subject to court approval); and any remaining balance distributed to the claiming class members to increase the amount of their claims on a *pro rata* basis;
- If the Settlement Amount is insufficient to pay all claims in full, the payments to members of the settlement class will be reduced *pro rata*.

### **ANALYSIS**

#### **IV. THE COURT SHOULD CERTIFY THE RULE 23 SETTLEMENT CLASS UNDER RULE 23(a) AND (b)**

The Court’s threshold task is to determine whether the settlement class satisfies the requirements of Rule 23(a), and at least one prong of Rule 23(b).<sup>1</sup> Here, the Court

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<sup>1</sup> Fed. R. Civ. P. 23.



can find that the Rule 23 settlement class easily meets the criteria of Rule 23(a). Additionally, because the Rule 23 settlement class meets the criteria of Rule 23(b)(2), certification under that prong is appropriate.

**A. The Rule 23 Settlement Class Satisfies the Criteria of Rule 23(a)**

Rule 23(a) requires the proponents of certification to establish that 1) members of the class are so numerous that joinder of all members is impracticable; 2) commonality exists among issues of law or fact raised by the class members; 3) the claims of the class representatives are typical of the claims of the absent class members; and 4) the class representatives will adequately represent the interests of the class. Fed. R. Civ. P. 23(a).<sup>2</sup>

**1. Members of the Rule 23 Settlement Class are so Numerous that Joinder of all Members is Impracticable**

Minnesota district courts have cited both *Newberg on Class Actions* and Moore's *Federal Practice* for the proposition that putative class sizes of 40 will support a finding of numerosity.<sup>3</sup> There are thousands of Third-Party Payors in the settlement class making joinder clearly impracticable. For settlement purposes, GSK has not disputed that numerosity exists.

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<sup>2</sup> While GSK does not concede these issues, it has, nonetheless, for settlement purposes only, agreed not to contest them.

<sup>3</sup> *Lockwood v. Gen. Motors, Inc.*, 162 F.R.D. 569, 574 (D. Minn. 1995).

## **2. Common Issues of Law or Fact Unite the Class Member Claims**

The threshold for finding commonality under Rule 23(a)(2) is not high. It requires only that there are “other members of the class who have the same or similar grievances as the plaintiff.”<sup>4</sup> The standard is “easily met” in most cases.<sup>5</sup>

Here, Plaintiffs allege that numerous common questions of law and fact applicable to the putative class exist with respect to the liability issues, relief issues and anticipated affirmative defenses. For example, common questions of fact include matters relating to GSK’s marketing and promotion practices of Paxil® and whether those practices were deceptive. Common questions of law include whether members of the putative class were entitled to refunds because consumers would not have purchased Paxil® for use by minors if they had known about its safety and efficacy profile. GSK’s defenses, including Article III standing, preemption and learned intermediary also provide common questions of law and fact.

## **3. The Claims of the Class Representatives are Typical of the Class**

Rule 23(a) also requires that the “claims or defenses of the representative parties [be] typical of the claims or defenses of the class.” Fed. R. Civ. P. 23(a)(3). The typicality inquiry works “to align the interests of the class and the class representatives so that the latter will work to benefit the entire class through the pursuit of their own

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<sup>4</sup> *Donaldson v. Pillsbury Co.*, 554 F.2d 825, 830 (8th Cir. 1977).

<sup>5</sup> *Lockwood*, 162 F.R.D. at 575 (citing Newberg).

goals.”<sup>6</sup> Accordingly, the typicality requirement focuses the district court on whether the representative plaintiffs’ claims arise from the same practice or course of conduct that gives rise to the claims of other class members or whether their claims are based on the same legal theory.<sup>7</sup> Typicality is satisfied when “the claims of the named plaintiffs emanate from the same event or are based upon the same legal theory as the claims of the class members.”<sup>8</sup> Even a “strong similarity of legal theories” will satisfy typicality despite substantial factual differences.<sup>9</sup> Thus, the typicality inquiry tends to merge with the commonality analysis.

Here, Plaintiffs’ claims are typical of the claims of the members of the Rule 23 Settlement Class. Each named plaintiff paid for or reimbursed its members for Paxil®

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<sup>6</sup> *Prudential.*, 148 F.3d at 31; *see also In re Control Data Corp. Sec. Litig.*, 116 F.R.D. 216, 220 (D. Minn. 1986) (citations omitted).

<sup>7</sup> *E. Tex. Motor Freight Sys., Inc. v. Rodriguez*, 431 U.S. 395, 403 (1977). Courts following these precepts have held that any differences between the class representative and the putative class must be material to the claims and defenses pled – not merely “incidental” to the allegations. *Lockwood*, 162 F.R.D. at 575-76. Accordingly, courts have held that the burden of demonstrating typicality is fairly easily met.” *DeBoer v. Mellon Mortgage Co.*, 64 F.3d 1171, 1174 (D. Minn. 1995). As the typicality inquiry often merges with the commonality analysis, the Eighth Circuit has given typicality an “independent meaning” by holding that Rule 23(a)(3) “requires a demonstration that there are other members of the class who have the same or similar grievances as the [class representative].” *Paxton v. Union Nat’l Bank*, 688 F.2d 552, 562 (8th Cir. 1982) (citation omitted); *Rexam Inc. v. United Steel Workers of Amer.*, No. 03-2998, 2005 WL 1260914, \*6 (D. Minn. May 25, 2005).

<sup>8</sup> *In re Workers’ Compensation*, 130 F.R.D. 99, 105 (D. Minn. 1990).

<sup>9</sup> *In re Hartford Sales Practices Litig.*, 192 F.R.D. 592, 603 (D. Minn. 1999).

prescribed to persons under the age of 18 years. Thus, Plaintiffs have alleged the same claims for themselves as they seek to certify for the class, and they rely on the same legal theories as all other Settlement Class Members.<sup>10</sup>

#### **4. Class Counsel and the Named Plaintiffs are Adequate**

Under Rule 23(a)(4) the representative parties must fairly and adequately protect the interests of the class. To fulfill this requirement, two factors must be satisfied: 1) “the representatives and their attorneys are able and willing to prosecute the action competently and vigorously, and 2) each representative’s interests are sufficiently similar to those of the class such that it is unlikely that their goals and viewpoints will diverge.”<sup>11</sup>

The question of competent and vigorous representation is met. The settlement class is represented by seven law firms from Minnesota, California, Texas, Illinois and Pennsylvania. Each of the firms handle complex litigation and have the required resources and capability. Class Counsel have a breadth and depth of experience in certifying, trying, and settling class actions. Additionally, this Court and other federal courts have repeatedly found the firms to be adequate class and MDL counsel.

The named Plaintiffs have no interests that are anything but identical to the Rule 23 settlement class. The representative Plaintiffs stand in the same factual and legal shoes as every other Settlement Class Member, and seek the same form of relief.

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<sup>10</sup> *In re Select Comfort Sec. Litig.*, 202 F.R.D. at 610.

<sup>11</sup> *Lockwood*, 162 F.R.D. at 576; see also *DeBoer*, 64 F.3d at 1175 (stating that there was “no indication that [Plaintiff’s] interest was antagonistic to the remainder of the class or that the claims were not vigorously pursued”).

Additionally, the representative Plaintiffs have shown their commitment to prosecute this matter, having supplied Class Counsel with essential factual information concerning their legal claims, answering interrogatories and document requests, and testifying at deposition when requested.

**B. The Rule 23 Settlement Class Should be Certified Under Rule 23(b)(3)<sup>12</sup>**

The settlement class may be certified under Rule 23(b)(3) because: 1) common questions of law or fact predominate over questions affecting only individual members; and 2) a class action is “superior to other available methods” of adjudicating the case.<sup>13</sup> Because a settlement obviates the need for the Court to determine the manageability of a litigation class, the case can be certified under Rule 23(b)(3) now. Rule 23(b)(3) also preserves a class members’ ability to opt out of the settlement insofar as the class members’ damages claims are concerned.<sup>14</sup>

**1. Common Issues of Fact and Law Predominate**

No bright line rules determine predominance under Rule 23(b)(3). Rather, the fundamental question is whether the group aspiring to class status is seeking to remedy a

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<sup>12</sup> While GSK does not concede these issues, it has, nonetheless, for settlement purposes only, agreed not to contest them.

<sup>13</sup> Fed. R. Civ. P. 23(b)(3).

<sup>14</sup> Fed. R. Civ. P. 23(c)(3).

common legal grievance. The Court looks to whether some elements of claims and defenses can be proven on a simultaneous, class-wide basis.<sup>15</sup>

Here, Plaintiffs and the Rule 23 settlement class that they hope to represent seek to remedy a common legal grievance concerning the costs of Paxil® prescribed to minors. The Settlement does just that – resolves and settles with finality all of the claims asserted against GSK.

## **2. A Class Action Settlement is the Superior Means of Resolving this Dispute**

Rule 23(b)(3)’s superiority analysis essentially looks to alternative methods of adjudication and whether maintenance of a class action would be fair and efficient to all parties.<sup>16</sup> Superiority is satisfied in the present case because: 1) Settlement Class Members have expressed little interest in individually controlling the prosecution of separate actions; 2) prosecuting or defending separate actions at this stage would be impractical and inefficient; and 3) to Plaintiffs’ knowledge there is no other litigation concerning this controversy.<sup>17</sup> In addition, “because the action is being settled, rather than litigated, the Court need not consider manageability issues that might be presented by the trial of a nationwide class action involving the issues in this case.”<sup>18</sup>

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<sup>15</sup> *Lockwood*, 162 F.R.D. at 610.

<sup>16</sup> *In re Workers’ Compensation*, 130 F.R.D. at 108 (noting that the real issue in determining superiority is the manageability of a case as a class action as opposed to the alternative—an individual action).

<sup>17</sup> Fed. R. Civ. P. 23(b)(3).

<sup>18</sup> *In re Lutheran Bhd. Variable Ins. Prods. Co. Sales Pracs. Litig.*, 99-MDL-1309, 2004

Resolution of the litigation by the parties' Settlement is superior to other available methods for a fair and efficient adjudication of the action because it avoids duplicative litigation of common issues and prevents the problem of contradictory outcomes. In addition, the Settlement reaches thousands. The resolution provides all Settlement Class Members with an opportunity to receive a refund for payments made for Paxil® used by minors.

**V. THE SETTLEMENT IS FAIR, REASONABLE AND ADEQUATE AND SHOULD BE APPROVED.**

Settlement is the preferred means of resolving litigation. *Williams v. Nat'l Bank*, 216 U.S. 582, 595 (1910); *Liddell v. Bd. Of Educ.*, 126 F.3d 1049, 1056 (8th Cir. 1997). Settlement of class actions is particularly appropriate because the costs, delays, risks, and uncertainties inherent in complex litigation might overwhelm any recovery the class stands to obtain. *White*, 822 F. Supp. at 1416 ("The policy in federal court favoring the voluntary resolution of litigation through settlement is particularly strong in the class action context."); 4 Newberg § 11.41. By supporting the settlement of complex class action disputes, the judicial system can help minimize litigation expenses on both sides, reduce the strain on scarce judicial resources, and avoid the risks of trial to both parties. *In re Gen. Motors Corp.*, 55 F.3d 768, 784 (3d Cir. 1995) (citing cases); 4 Newberg §11.41; Ann. Man. at §§ 23, 30.4.

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WL 2931352, at \*8 (D. Minn. Dec. 16, 2004).

Nevertheless, in a class action brought under Rule 23 of the Federal Rules of Civil Procedure the district court must oversee the resolution because the court, like the representatives and Class Counsel, assumes a fiduciary duty to absent Settlement Class Members.

At the final approval hearing the Court will have the opportunity to hear additional evidence and argument concerning the fairness, adequacy and reasonableness of the settlement, as well as class members' reaction to the settlement. Ann. Manual § 30.41 at 236-37.

#### **A. Standard for Approval**

While the decision to approve a proposed settlement is committed to the Court's sound discretion, courts attach "[a]n initial presumption of fairness...to a class settlement reached in arm's length negotiations between experienced and capable counsel after meaningful discovery." *Grier v. Chase Manhattan Auto. Fin. Co.*, No. 99-180, 2000 WL 175126, \*5 (E.D. Pa. Feb. 16, 2000) (citation omitted); *see also Grunin v. Int'l House of Pancakes*, 513 F.2d 114, 123 (8th Cir. 1975); *White v. Nat'l Football League*, 836 F. Supp. 1458, 1476-77 (D. Minn. 1993); 4 Herbert B. Newberg & Alba Conte, *Newberg on Class Actions* ("Newberg") § 11.24 (4th ed. 2002). "The Court is entitled to rely on the judgment of experienced counsel in its evaluation of the merits of a class action settlement." *In re Employee Benefit Plans Sec. Litig.*, No. 3-92-708, 1993 WL 330595, \*5 (D. Minn. June 2, 1993); *see also Welsch v. Gardebring*, 667 F. Supp. 1284, 1295 (D. Minn. 1987) (giving "great weight" to opinions of experienced counsel); *In re*



*Coordinated Pretrial Proceedings in Antibiotic Antitrust Actions*, 410 F. Supp. 659, 667 (D. Minn. 1974) (same).

In the same vein, a court considering a motion for approval neither decides the merits of the underlying case, nor crafts a settlement for the parties. *Grunin*, 513 F.2d at 123 (“neither the trial court in approving the settlement nor this Court in reviewing the approval have the right or duty to reach any ultimate conclusions on the issues of fact and law which underlie the merits of the dispute”); *see also White*, 836 F. Supp. at 1477 (“the court does not have the responsibility of trying the case or ruling on the merits of the matters resolved by agreement . . . . Rather, ‘the very purpose of compromise is to avoid the delay and expense of such a trial’”); *Holden v. Burlington Northern, Inc.*, 665 F. Supp. 1398, 1403 (D. Minn. 1987) (recognizing district court’s approval was not expression of its opinion about merits).

**B. The Settlement Provides Substantial Relief for Class Members and Should Be Preliminarily Approved**

With a total payment of \$40 million, this Settlement clearly provides a significant, substantial amount to Settlement Class Members. A primary advantage of the Settlement for Settlement Class Members is that their claim amount is keyed to their total outlay for Paxil® prescriptions dispensed for persons under age 18. Thus, the Settlement not only accounts for risks in establishing GSK’s factual and legal liability, but also removes the burden of showing causation of damages. These risks can be summarized briefly.

Although the FDA has not approved use of Paxil® in minors, Plaintiffs must concede that physicians may prescribe a drug for “off-label” use, even though a

manufacturer is not allowed to promote such use. Thus, one of GSK's primary defenses is the learned intermediary doctrine in multiple forms, couched in concepts of reliance, causation, and duty. GSK contends that doctors made independent decisions based on their training, experience and medical judgment, a process that breaks any chain of causation. GSK denies that it engaged in any improper promotion, but claims that even if Plaintiffs can show such promotion, they cannot establish that any particular doctor's decision for any particular patient was influenced, to the point of "but-for" causation, by particular promotional conduct. In addition, Paxil® has at all relevant times indicated on its labeling that the FDA had not approved the drug for children. At the certification stage, GSK would likely contend that the difficulty of proof is compounded because every putative class member must make such a showing for every prescription paid.

Class Counsel believe the Plaintiffs' claims in this case are strong. At the same time, dispositive motions remain pending in some cases and others were expected. Nor can counsel ignore recent preemption decisions from the Supreme Court of the United States and other courts of appeal, that present challenges to a claim against the pharmaceutical manufacturer where conduct, warnings, or promotion was subject to some level of approval or regulation by the FDA.

These and other risks and obstacles, both on factual and legal grounds, strongly inform the judgment of Plaintiffs' counsel that a settlement allowing Settlement Class Members to recover up to 40% of their total Paxil® purchases for minors, without any proof other than a printout of data showing the patient's age, diagnostic code, amount paid, and related certifications, is eminently reasonable. The fact that different sets of

Plaintiffs' counsel, each pursuing different cases in Minnesota, California, and Pennsylvania, have joined to endorse the Settlement confirms both the arm's-length character of the negotiations, as well as the considered opinion of counsel in favor of the Settlement.

## **VI. THE PROPOSED SETTLEMENT SHOULD BE APPROVED BECAUSE IT IS PRESUMPTIVELY FAIR, REASONABLE AND ADEQUATE**

The fundamental criteria the Court must determine is whether the settlement is "fair, reasonable, and adequate." Fed. R. Civ. P. 23(e)(1)(C); *see also Prudential*, 148 F.3d at 316.<sup>19</sup> District courts begin their analysis with a presumption that a proposed settlement is fair and valid:

[A] presumption of fairness exists where: (1) the settlement is reached through arm's-length bargaining; (2) investigation and discovery are sufficient to allow counsel and the court to act intelligently; (3) counsel is experienced in similar litigation; and (4) the percentage of objectors is small.

4 Newberg at § 11.41; *see also Little Rock School Dist. v. Pulaski County Special School Dist. No. 1*, 921 F.2d 1371, 1391 (8th Cir. 1990) (recognizing that settlements are presumptively valid); *Ellis v. Naval Air Rework Facility*, 87 F.R.D. 15, 18 (N.D. Cal 1980) (analyzing above-cited factors); accord *Grier*, No. 99-180, 2000 WL 175126, at \*5 (E.D. Pa. Feb. 16, 2000)(same); *Manual* at § 30.41.

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<sup>19</sup> Ann. Manual § 21.632. As described in the *Manual for Complex Litigation*: Fairness calls for a comparative analysis of the treatment of class members vis-à-vis each other and vis-à-vis similar individuals with similar claims who are not in the class. Reasonableness depends on an analysis of the class allegations and claims and the representativeness of the settlement to those claims. Adequacy involves a comparison of the relief granted relative to what class members might have obtained without using the class action process.

Before reaching the Settlement, the parties in the four cases engaged – to varying degrees – in extensive factual investigation and thorough discovery. The parties exchanged hundreds of thousands of pages of documents and deposed dozens of witnesses. Plaintiffs retained numerous liability and damages experts and disclosed those experts in several of the cases. Settlement was not reached until GSK had sought dismissal of all four cases and after class certification had been partially briefed in one of the cases.

The parties negotiated the Settlement in good faith and at arm's length. This deal was reached only after hard-fought settlement negotiations that took place over the course of a number of different in-person sessions held across the country. Counsel for each of the parties consider the Settlement to be a fair resolution of their respective differences based upon the numerous rulings received in the courts handling these cases and elsewhere. In light of their experience, the Court should accord their assessment considerable weight. *Grier*, 2000 WL 175126 at \*5. Thus, counsel for each of the parties—who are experienced plaintiffs' class action and defense attorneys—have fully evaluated the strengths, weaknesses, and equities of the parties' respective positions. This factor supports the fairness and reasonableness of a class action settlement. See *Ellis*, 87 F.R.D. at 18 (citing cases and authorities). Moreover, this Settlement was achieved after the litigation had been conducted for nearly four years and was therefore mature.

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Manual, § 21.62, at 315.

In addition, the Settlement does not give undue preferential treatment to the named Plaintiffs or other members of the Class, or permit excessive attorneys' fees. Subject to Court approval, Plaintiffs will seek service awards for the class representatives, to be paid from the fee award. Such awards are routine, appropriate, and serve public policy by encouraging parties to come forward to protect the rights of others, while at the same time compensating the class representatives for their time, effort, and inconvenience – including responding to discovery and testifying at depositions – in representing the interests of the putative class.

The Settlement provides that attorneys' fees and costs will be paid from the Settlement Amount. Class Counsel will ask for no more than one-third of the Settlement Amount, to cover their fees and incurred costs, as well as the incentive awards to the named plaintiffs. The expected costs and expenses of class administration will also be paid out of the Settlement Amount. In a separate Motion, Class Counsel are seeking the Court's review and approval for an award of attorneys fees and costs, including incentive payments to the named plaintiffs.

Given the significant amount of work done in this case over a four-year period, the amount of risk and cost associated with the litigation and the benefits provided to the Class, the parties' agreement on fees and costs is well within the range of reasonableness.

**VII. OTHER FACTORS SUPPORT THE CONCLUSION THAT THE SETTLEMENT IS FAIR, REASONABLE AND ADEQUATE.**

In addition to being presumptively valid, the Settlement meets the Eighth Circuit's additional fairness criteria. These criteria include: 1) the merits of the plaintiff's case,

weighed against the terms of the settlement; 2) the defendant's financial condition; 3) the complexity and expense of further litigation; and 4) the amount of opposition to the settlement.<sup>20</sup> *In re Wireless Tel. Fed. Cost Recovery Fees Litig.*, 396 F.3d 922, 932-33 (8th Cir. 2005) (citing *Grunin*, 513 F.2d at 124).

#### **A. Merits and Risks of Claims Favor Settlement**

Under the Eighth Circuit's test, "[t]he most important consideration in deciding whether a settlement is fair, reasonable, and adequate is 'the strength of the case for plaintiffs on the merits, balanced against the amount offered in settlement.'" *In re Wireless Tel. Fed. Cost Recovery Fees Litig.*, 396 F.3d at 933 (citing *Petrovic v. Amoco Oil Co.*, 200 F.3d 1140, 1150 (8th Cir. 1999) (internal quotations omitted)). While a weighing of the merits is required, the Court is not to "go beyond the amalgam of delicate balancing, gross approximations, and rough justice." *White*, 836 F. Supp. at 1477 (internal citations omitted).

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<sup>20</sup> These factors parallel the nine-factor balancing test described by the Third Circuit, which is embraced by both the annotations to Rule 23(e) and the *Manual for Complex Litigation. Prudential*, 148 F.3d at 317. While not controlling in this Circuit, those factors are:

- 1) the complexity, expense, and likely duration of the litigation; 2) the reaction of the class to the settlement; 3) the stage of the proceedings and the amount of discovery completed; 4) the risks of establishing liability; 5) the risks of establishing damages; 6) the risks of maintaining the class action through trial; 7) the ability of the defendants to withstand a greater judgment; 8) the range of reasonableness of the settlement fund in light of the best possible recovery; [and] 9) the range of reasonableness of the settlement fund to a possible recovery in light of all the attendant risks of litigation.

*Id.*

Applying these factors to the Settlement, the Court can easily find that the requisites of Rule 23(e) have been met. *First*, while Plaintiffs and Class Counsel believe their case is meritorious and supported by ample precedent, they face several defenses that, if successful, might defeat part or all of Plaintiffs' claims even prior to trial. For example, GSK maintains that Plaintiffs' entire cause of action is barred by federal preemption of claims relating to prescription drugs. Similarly, GSK has asserted that the Third-Party Payors lack standing to bring these claims, and that the learned intermediary doctrine completely bars the suits.

Accordingly, while Class Counsel believe that Plaintiffs' claims are strong, counsel are also experienced and realistic enough to know that the guaranteed recovery and certainty achieved through settlement—as opposed to the uncertainty inherent in the jury trial and appellate process—weighs heavily in favor of the Settlement. Here, all Settlement Class Members will receive monetary relief. Thus, aside from the obvious risk that Plaintiffs bear—that they would achieve no recovery for anyone at trial—it is also possible, due to any subclass structure of a litigated case, that only some Plaintiffs would prevail. Through the Settlement, everyone has a chance to receive compensation.

**B. Defendant's Financial Condition Supports Settlement**

*Second*, no dispute exists concerning GSK's ability to pay the Settlement Amount. This weighs heavily in favor of approval.

**C. Expense and Burden of Continued Litigation Support Settlement**

*Third*, continued litigation in these cases would involve a set of trials that would clearly increase the expense to the parties, add to the complexity of this litigation, and tax already limited judicial resources.

However the claims and defenses would be resolved, their legal and factual complexity make them expensive to litigate on a class-wide basis. Evaluation of all claims and defenses may entail expert analysis and testimony, statistical modeling, extensive document reviews, and other daunting procedures. These defenses are hot-button issues in prescription drug cases, and their application here presents substantial risks to both parties. If fully litigated, they could take years to resolve through verdict and judgment, and, inevitably, appeal.

Aside from the extensive non-dispositive and dispositive motions already completed in the four cases, class certification briefing and argument was underway in one of the cases and was largely inevitable in the others. Trials would have taken weeks or months in each of the four cases. Any class, subclass or individual plaintiff that advanced to a verdict would inevitably have been subject to additional process consisting of lengthy post-trial motions, and, given the high stakes nature of the case, appeals. This would only result in more delay in recovery, if Plaintiffs ultimately prevailed. As this Court noted in another context, “[l]engthy litigation is hard on any party.” *Rexam*, 2007 WL 2746595 at\*5. The proposed Settlement therefore eliminates the need for lengthy, uncertain, and expensive trials.



**D. Reaction of Class Members Supports Settlement**

*Fourth*, evidence shows that the Settlement has been favorably received by the class. Each of the class representatives has given its approval to the Settlement.

The class response should be placed in context. Direct notice was mailed to some 43,000 potential class members. Out of that large number of sophisticated medical expense payors, only 85, about 0.2 % of the total, chose to exclude themselves from the class. Thus, the overwhelming majority of class members elected to participate in the settlement.

**1. Minuscule Proportion of Exclusions Show Broad Approval for the Settlement**

The small number of exclusion requests fell into three categories.

First, a small number of self-insured employers' plans, less than 10, opted out on their company letterhead. These entities included the Woods Hole Marine Biological Laboratory, A. M. Best Company, the Christian Broadcasting Network, and Dunbar Armored. The exclusions did not give any reasons, but likely reflect a corporate policy or philosophy against participation in class actions in general, rather than any particular dissatisfaction with the terms of the settlement.

Second, a number of health insurers, for-profit companies as well as regional Blue Cross organizations, all represented by the same law firm, had previously excluded themselves from the class-action settlement over Paxil pricing and generic competition, *Nichols v. SmithKline Beecham Corp*, 2005 U.S. Dist. LEXIS 7061 (E.D. Pa., No. 00-6222, 2005). These companies jointly filed a lawsuit raising those pricing claims against

GSK in Minnesota state court. Reportedly, counsel for these insurers was concerned that the pending pricing claims might be affected by the release terms in this case. Thus, the basis for these exclusions was not dissatisfaction with the terms of this settlement per se, but rather because these entities are pursuing an individual action that overlaps with these claims. The undersigned counsel expect that all those claims will be resolved outside the scope of this settlement.

Third, two other law firms filed exclusions on behalf of a variety of health insurers. These entities had not filed any previous cases to recover Paxil costs against GSK. As a result of the discussions and modifications to the agreement, as describe herein, these two firms are prepared to recommend that their clients withdraw their exclusions and participate in this settlement.

Under the terms of the settlement agreement, GSK had the right to terminate the settlement if the covered lives represented by exclusion requests exceeded a given threshold. The clients of those three law firms represented covered lives well in excess of the threshold.

As a result of intense discussions among all involved parties, agreement has been reached on modified terms that permit the settlement to go forward, to the benefit of all participating class members, provided that the pending objections are withdrawn (as is expected as of this filing). These modifications allow a possibility of an upward *pro rata* adjustment, as well as a simplified claims process that would not require deduction for discounts and rebates.

**2. Objections, to the Extent They Have Merit, Are Incorporated in Modified Agreement**

As far as objections, the Court received only one objection, and that lone objection is expected to be withdrawn in recognition of the modifications to the agreement from its original proposed form. In the event that the objection is not withdrawn as expected, the parties will address the merits of the objection at the final fairness hearing.

**CONCLUSION**

The proposed Settlement provides a substantial, certain recovery to a nationwide class of Third-Party Payors, against a formidable array of legal, factual, and procedural obstacles. The Settlement meets the criteria for final approval.

Therefore, the parties request entry of an Order in the form attached.

Respectfully submitted,

DATE: September 9, 2008

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